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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,232	09/08/2003	Saverio Carl Falco	BB1179 US CIP	6058

23906 7590 07/05/2005

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EXAMINER	
RAMIREZ, DELIA M	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,232	FALCO ET AL	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-19 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 17-18, drawn in part to a polynucleotide encoding the polypeptide of SEQ ID NO: 6, a method for transforming a cell with said polynucleotide, a method for isolating said polypeptide from a culture comprising said cell, and a method of producing said polypeptide by culturing said cell, classified in class 435, subclass 69.1.

II. Claims 1, 3-4, 6-9, 17-18, drawn in part to a polynucleotide encoding the polypeptide of SEQ ID NO: 17, a method for transforming a cell with said polynucleotide, a method for isolating said polypeptide from a culture comprising said cell, and a method of producing said polypeptide by culturing said cell, classified in class 435, subclass 69.1.

III. Claims 10-12, drawn in part to a transgenic plant, seed and a method for producing said plant by transforming said plant with a polynucleotide encoding the polypeptide of SEQ ID NO: 6, classified in class 800, subclass 278.

IV. Claims 10-12, drawn in part to a plant, seed and a method for producing said plant by transforming said plant with a polynucleotide encoding the polypeptide of SEQ ID NO: 17, classified in class 800, subclass 278.

V. Claims 13-16, drawn in part to a polypeptide comprising SEQ ID NO: 6, classified in class 435, subclass 191.

VI. Claims 13, 15-16, drawn in part to a polypeptide comprising SEQ ID NO: 17, classified in class 435, subclass 191.

VII. Claim 19, drawn in part to a method for testing compounds for their ability to inhibit the 5,10-methylenetetrahydrofolate reductase activity of the polypeptide of SEQ ID NO: 6, classified in class 435, subclass 25.

VIII. Claim 19, drawn in part to a method for testing compounds for their ability to inhibit the 5,10-methylenetetrahydrofolate reductase activity of the polypeptide of SEQ ID NO: 17, classified in class 435, subclass 25.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I-VI each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The nucleic acids of Groups I-II comprise purine and pyrimidine units, the proteins of Groups V-VI comprise amino acids, and the transgenic plants of Groups III-IV are multicellular organisms. Thus the products of Groups I-VI are structurally distinct. While the proteins of Groups V-VI have been disclosed as having 5,10-methylenetetrahydrofolate reductase activity, they are distinct proteins as they comprise a different amino acid sequence. Similarly, the nucleic acids of Groups I-II while encoding proteins having 5,10-methylenetetrahydrofolate reductase activity are distinct nucleic acids as they comprise a different nucleotide sequence. Furthermore, while the transgenic plants of Groups III-IV comprise polynucleotides encoding proteins having 5,10-methylenetetrahydrofolate reductase activity, they are distinct products as these polynucleotides comprise different nucleotide sequences. The nucleic acids of Groups I-II have other uses besides encoding the proteins of Group V-VI or being introduced in the transgenic plants of Groups III-IV, such as a hybridization probe or in gene therapy. The transgenic plants of Groups III-IV can have other uses such as to produce specific compounds which are naturally found in such plants and/or their fruits, if they are fruit-bearing plants, besides manufacturing the proteins of Groups V-VI. The proteins from Groups V-VI can be prepared by processes which are materially different from recombinant expression of the polynucleotides of Groups I-II or expression in the

transgenic plants of Groups V-VI, such as by chemical synthesis, or by isolation and purification from natural sources.

3. Inventions V-VI and VII-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Inventions V-VI can be used to elicit antibodies as well as in the methods of Inventions VII-VIII.

4. Inventions I-II and VII-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Inventions I-II can be used to produce the proteins of Inventions V-VI, the transgenic plants of Inventions III-IV, as well as in the methods of Inventions VII-VIII.

5. Inventions III-IV and VII-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the transgenic plants of Inventions III-IV are neither used nor made by the methods of Inventions VII-VIII

6. As set forth in MPEP § 803, the criteria for a proper restriction between patentably distinct inventions requires that the inventions must be independent or distinct as claimed, and a search of all the inventions would impose a serious burden on the examiner. Groups I-VIII have been shown to be independent or distinct, for the reasons set forth above. MPEP § 803 also indicates that a serious burden on the examiner may be prima facie shown if the Examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. The inventions of Groups I-

VIII have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification. In addition, a search of all the inventions would require at a minimum a separate patented/non-patented literature search and a class/subclass search. These searches are not all co-extensive. Therefore a comprehensive examination of all groups would impose an undue burden on the Examiner. Thus, restriction for examination purposes as indicated is proper.

7. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

8. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may

result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

10. It is noted that if the same claim is in multiple Groups, such claim will be examined to the extent it reads on the elected invention.

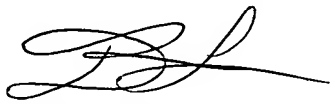
11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (571) 273-8300. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
June 24, 2005